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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR			ATTORNEY DOCKET NO.
08/961,083	10/30/97	CHOI		G	PB340P2
— HUMAN GENOME SCIENCES 9410 KEY WEST AVENUE		HM32/1026	\neg		EXAMINER
			•	HINES,	
ROCKVILLE N				ART UNIT	PAPER NUMBER
				1641	5
•				DATE MAILED:	10/26/ 9 8

PI ase find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 08/961,083

Applicant(s)

Choi, et al

Examiner

Ja-Na Hines

Group Art Unit 1641



⊠ Responsive to communication(s) filed on Oct 30, 199	7
☐ This action is FINAL .	
Since this application is in condition for allowance exc in accordance with the practice under Ex parte Quayle	cept for formal matters, prosecution as to the merits is closed e, 1935 C.D. 11; 453 O.G. 213.
is longer, from the mailing date of this communication. F	s set to expire month(s), or thirty days, whichever Failure to respond within the period for response will cause the Extensions of time may be obtained under the provisions of
Disposition of Claims	
	is/are pending in the application.
Of the above, claim(s)	is/are withdrawn from consideration.
Claim(s)	
Claim(s)	
Claim(s)	
	are subject to restriction or election requirement.
Application Papers ☐ See the attached Notice of Draftsperson's Patent I	Drawing Review, PTO-948.
☐ The drawing(s) filed on is/are	objected to by the Examiner.
☐ The proposed drawing correction, filed on	is approved disapproved.
☐ The specification is objected to by the Examiner.	
$\hfill\Box$ The oath or declaration is objected to by the Exam	iner.
Priority under 35 U.S.C. § 119	
Acknowledgement is made of a claim for foreign p	
☐ All ☐ Some* ☐ None of the CERTIFIED co	opies of the priority documents have been
received.	
received in Application No. (Series Code/Ser	
received in this national stage application fro	om the International Bureau (PCT Aule 17.2(a)).
*Certified copies not received: Acknowledgement is made of a claim for domestic	priority under 35 U.S.C. § 119(e).
•	
Attachment(s) Notice of References Cited, PTO-892	
☐ Information Disclosure Statement(s), PTO-1449, P	aper No(s).
☐ Interview Summary, PTO-413	
☐ Notice of Draftsperson's Patent Drawing Review,	PTO-948
☐ Notice of Informal Patent Application, PTO-152	
SEE OFFICE ACTIO	ON ON THE FOLLOWING PAGES

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DETAILED ACTION

The preliminary amendment filed October 30, 1998 contained numerous species within its application, accordingly the restriction requirement of September 24, 1998 is hereby vacated in favor of the modified restriction requirement set forth below.

Revised Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9, 13 are drawn to an isolated nucleic acid molecule, a method of making a recombinant vector, a method for producing a polypeptide and the polynucleotide encoding a polypeptide classified in class 424, subclass 185.1.
 - II. Claim 10-12, 16 and 20 are drawn to a polypeptide, a polypeptide antigen, a vaccine and a kit for detecting *Streptococcus* classified in class 424, subclass 184.1.
 - III. Claims 14-15, are drawn to an antibody and a hybridoma which produces the antibody, classified in class 424, subclass 141.1.
 - IV. Claim 17, is drawn to a method of preventing infection, classified in class 424, subclass 900.
 - V. Claim 18 and 19, are drawn to a method of detecting *Streptococcus* under conditions such that hybridization occurs and a method of detecting *Streptococcus* using polymerase chain reaction, classified in class 424, subclass 9.1.

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- VI. Claim 21, is drawn to a method of detecting *Streptococcus* using antibody-antigen complexes, classified in class 435, subclass 7.1.
- 2. The inventions are distinct, each from the other because of the following reasons:
- 3. Inventions in group I and II-VI are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(I)).
- 4. Inventions in groups I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the individual groups each disclose a different use for the products claimed.
- 5. Inventions in groups II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are claimed in groups II and III. There are different modes of operation function and effects since group II makes a polypeptide, an antigen, a vaccine and a kit used for detection while group III makes an antibody and a hybridoma cell.
- 6. Inventions in group IV and groups I-III and V-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

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modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case group IV claims a method of prevention while the other groups do not disclose similar inventions.

- 7. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions in group V are drawn to a materially different method of detection then group VI.
- 8. Because these inventions are distinct for the reasons given above and the search required for any one of the twelve groups is not required for any of the other groups, restriction for examination purposes as indicated is proper.
- 9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 11. Claims within groups II, III, IV and VI are to a plurality of disclosed patentably distinct products comprising materially different proteins. Should the inventions of groups II, III, IV or VI be elected, Applicant would be required under 35 U.S.C. 121 to elect a single disclosed

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product, even though this requirement is traversed. The separate proteins bear no structural or biochemical property in common and therefore each particular protein product claimed and would require a separate area of search and consideration tailored to the particular product under consideration.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. In addition to the preceding restriction requirement, upon election of group I or V, the following additional election would be required:

Claims in groups I or V are drawn to isolated nucleic acid molecules that contain more than ten individual, independent and distinct nucleotide sequences in alternative form.

Accordingly, these claims are subject to restriction under 35 U.S.C. § 121 as outlined in 1192 O.G. 68 (Nov. 19, 1996).

Applicant is required to select no more than ten of the individual sequences for examination. The search of no more than ten selected sequences may include the complements of the selected sequences and, where appropriate, may include sequences within the selected sequences (e.g. oligomeric probes and/or primers).

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- 13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).
- 14. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

APPLICANT IS GIVEN THE TIME WITHIN THIS ACTION WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response.

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Any inquiry concerning this communication or earlier communications from the examiner 15. should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Friday from 6:30am to 4:00pm except for the second Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

October 26, 1998